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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,060	07/25/2001	Sigrid Cornelis	4976US	6077

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EXAMINER	
PAPPU, SITA S	7
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/19/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application N .	Applicant(s)	
	09/915,060	CORNELIS ET AL.	
	Examiner	Art Unit	
	Sita S Pappu	1632	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed July 25, 2001 (Paper No. 4) has been entered. Claims 3, 11, 12, 14, 17, and 20 have been amended.

Applicant's election of Group-I, claims 1-15, 16-19, 22, without traverse, is acknowledged. Accordingly, non-elected claims 20, and 21 are cancelled without prejudice or disclaimer. New claims 23 and 24 are added.

Claims 1-19, 22-24 are pending in the instant application. This paper contains an examination of the claims, 1-19, 22-24 on their merits.

Drawings

The draftsperson objected to the drawings. The drawings are acceptable for examination purposes only. See attached PTO-948.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Xiang et al. (1994; Journal of biological chemistry, vol. 269, no.22, pp 15786-15794).

Claims 1-12 and 22 are directed an isolated and/or recombinant nucleotide sequence enabling a cell cycle dependent initiation of mRNA, wherein the nucleotide sequence is an internal ribosomal entry site sequence, and

wherein the cell cycle dependency is a G2/M cell cycle dependency and the nucleotide sequence further comprising SeqID NO: 1, or 4, or, 5, or 6 or a functional part of Seq ID NO: 1 or a nucleotide sequence at least substantially homologous to Seq ID NO: 1 or its complementary sequence.

Xiang et al. (1994) teach the cloning and expression of alternatively translated PITSLRE protein kinase isoforms. In particular they teach the nucleotide sequence of α2-2 p110 and its alternatively translated isoform p58 (see page 15786, left column, paragraph 4, line 3 with the GenBank accession number for α2-2 and page 15790, left column depicting the protein sequence of α2-2 isoform of PITSLRE kinases; page 15789, right column, paragraph 2, and the bridging paragraph of pages 15789-15790). These sequences comprise the IRES of Seq ID No: 1 of the instant invention as well as the Seq ID Nos. 4, 5, 6 and 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-16, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiang et al. (1994).

Claims 13-16, 23, 24 are directed to a chimeric gene comprising one of the above sequences in a vector and an expression system comprising the eukaryotic host cell, a method for cap-independent translation of mRNA in a cell.

Xiang et al. (1994) teach expression of the β1 isoform of PITSLRE protein kinases, that is substantially homologous to the α2-2 isoform, in a reticulocyte lysate cell system through the use of a vector (see page 15787, paragraph 2 in Experimental Procedures, lines 1-5 and lines 31-34).

Xiang et al. (1994) teach the nucleotide sequence of the α2-2 isoform of the instant case. However, they do not teach the expression in a eukaryotic cell with the α2-2 isoform of PITSLRE kinases.

Considering the substantial homology between the two isoforms as indicated by Xiang et al. (1994) in Figure 3 on page 15790, it is obvious that similar results would have been achieved if the α2-2 isoform was used in place of the β1 isoform in the studies done by Xiang et al. (1994). It is well known in the art that isoforms and isolates of genes and organisms behave similarly when there is high sequence homology between the said genes and/or organisms.

Therefore, it would have been obvious to one of ordinary skill in the art, to substitute the β1 isoform in the vector with the α2-2 isoform, with a reasonable

expectation of success, and arrive at a similar result of expression in eukaryotic cells.

The motivation to do so was provided by the statement of Xiang et al. (1994) who proposed that p58 protein kinase might function as a mitotic check point (page 15786, right column, lines 8-13) and that the identification of additional PITSLRE protein kinase family members will aid studies to determine the nature of the putative tumor suppressor gene and that the tight genetic linkage of the PITSLRE gene complex to the tumor suppressor locus recently mapped in both human and mouse, as well as the potential involvement of the PITSLRE α1 and β1 proteins in apoptosis, make them excellent candidates for this tumor suppressor gene (pages 15793 and 15794, bridging paragraph). This would provide sufficient motivation for one of ordinary skill in the art to substitute the β1 isoform of Xiang et al (1994) with the α2-2 isoform and conduct similar studies.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xiang et al. (1994) further in view of Parsels et al. (1998; Cancer journal from Scientific American vol.4, no.5, pp.287-295).

Claims 17-19 are directed to a method of inducing a cell cycle dependent initiation of translation in a eukaryotic cell, said method comprising introducing the isolated and/or recombinant nucleotide sequence of the instant invention into said eukaryotic cell, wherein the said nucleotide sequence is a G2/M dependent internal ribosome entry site sequence.

Xiang et al. (1994) teach expression of the β1 isoform, that is substantially homologous to the α2-2 isoform, in a reticulocyte lysate cell system through the use of a vector (see page 15787, paragraph 2 in Experimental Procedures, lines 1-5 and lines 31-34).

Xiang et al. (1994) do not teach the expression in a eukaryotic cell with the α2-2 isoform of PITSLRE kinases. Further, they do not teach the G2/M cell cycle dependency of the initiation of translation.

Parsels et al. (1998) describe various nucleotide sequences enabling cell cycle dependent initiation of translation of mRNA, and the role of translational regulation in the control of cell cycle associated pathways (page 293, left column, conclusion). Parsels et al. (1998) mention the role of p53 in the induction of p21 at the G/S and G2/M checkpoints (page 289, left column, paragraph 2 to right column, paragraph 1).

Parsels et al. (1998) do not teach the cell cycle dependent initiation of translation of the nucleotide sequence of the instant case.

The motivation to do so was provided by the statement of Xiang et al. (1994) who proposed that p58 protein kinase might function as a mitotic check point (page 15786, right column, lines 8-13) and that the identification of additional PITSLRE protein kinase family members will aid studies to determine the nature of the putative tumor suppressor gene and that the tight genetic linkage of the PITSLRE gene complex to the tumor suppressor locus recently mapped in both human and mouse, as well as the potential involvement of the PITSLRE α1 and β1 proteins in apoptosis, make them excellent candidates for

this tumor suppressor gene (pages 15793 and 15794, bridging paragraph). This would provide sufficient motivation for one of ordinary skill in the art to substitute the β1 isoform of Xiang et al (1994) with the α2-2 isoform and conduct similar studies.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sita S Pappu whose telephone number is (703) 305-5039. The examiner can normally be reached on Mon-Fri (9:00 AM - 5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached on (703) 305-6608. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-8724 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-2758.

Anne-Marie Baker

ANNE-MARIE BAKER
PATENT EXAMINER

S. Pappu
December 13, 2001